<T22AH7>

### Article 7. CABG Data Reporting Requirements

## <T22S97170>

#### § 97170. Definitions, as Used in this Article.

- (a) California CABG Outcomes Reporting Program (CCORP). California CABG Outcomes Reporting Program means the Office's program charged with collecting coronary artery bypass graft (CABG) surgery data and publishing reports on the risk-adjusted outcomes for the procedure.
- (b) Computer system date. Computer system date means the date that exists on the computer system used for data automation at the time of data entry.
- (c) Coronary artery bypass graft (CABG) surgery. CABG surgery means a procedure performed to bypass blockages or obstructions of the coronary arteries, and includes both isolated CABG surgeries and non-isolated CABG surgeries, as defined by Subsection (a)(2) of Section 97174.
  - (d) Days. Days are defined as calendar days unless otherwise specified.
- (e) Designee. Designee means the person authorized by the Chief Executive Officer of the hospital to sign the CCORP Hospital Certification Form (OSH–CCORP 416 (New 10/02).
- (f) Discharge. A discharge means a person who was formally admitted to a hospital as an inpatient for observation, diagnosis, or treatment, with the expectation of remaining overnight or longer, and who is discharged under one of the following circumstances:
  - (1) is formally discharged from the care of the hospital and leaves the hospital,
- (2) transfers within the hospital from one type of care to another type of care, as defined in Section 97212 of Title 22 of the California Code of Regulations, or
  - (3) has died.
- (g) Facility identification number. Facility identification number means the unique six-digit number assigned to each hospital by the Office, pursuant to Section 97210 of Title 22 of the California Code of Regulations.
- (h) Licensee. Licensee means an entity that has been issued a license to operate a hospital, as defined in the Health and Safety Code Section 128700.
- (i) Record. Record means the set of data elements required to be reported for each CABG surgery, as set forth in Section 97174.
- (j) Report. Report means the collection of all required records filed by a hospital for a reporting period, pursuant to Section 97172.
- (k) Responsible surgeon. Responsible surgeon means the principle surgeon who performs a coronary artery bypass procedure. If a trainee performs this procedure, then the responsible surgeon is the physician responsible for supervising this procedure performed by the trainee. In situations in which a responsible surgeon cannot otherwise be determined, the responsible surgeon is the surgeon who bills for the coronary artery bypass procedure. NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

HISTORY

1. New article 7 (sections 97170–97198) and section filed 4–29–2003; operative 4–29–2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

## <T22S97172>

#### § 97172. Required Reporting.

- (a) A hospital where coronary artery bypass graft (CABG) surgery is performed shall file a report, as defined in Section 97005 of Title 22 of the California Code of Regulations, semiannually with the Office. This Section shall not apply to a hospital where all CABG surgeries performed are on patients under 18 years of age on the date of surgery.
- (b) A report shall contain a record for each CABG surgery patient 18 years or older on the date of surgery who was discharged from the hospital during the reporting period, pursuant to Section 97176.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

History

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

## <T22S97174>

### § 97174. Required Data Elements.

- (a) A hospital shall submit the following data elements for each CABG surgery according to the format, valid value, and definitions/descriptions listed herein:
  - (1) Medical Record Number:
  - (A) Format: Text length 11
  - (B) Valid Values: Not defined.
  - (C) Definition/Description: Patient medical record number at the hospital where surgery was performed.
  - (2) Isolated CABG:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
- (C) Definition/Description: Answer 'No' if any of the procedures listed in Subsection (a)(2)(C)(i) was performed during coronary artery bypass graft surgery.
- (i) When any of the procedures listed in this Subsection is performed concurrently with the coronary artery bypass surgery, the surgery will be considered non–isolated and the data element coded 'No.' It is not possible to list all procedures because cases can be complex and clinical definitions are not always precise. When in doubt, the data abstractor should first seek an opinion from the responsible surgeon and then consult CCORP.

- (a) Valve repairs or replacements
- (b) Operations on structures adjacent to heart valves (papillary muscle, chordae tendineae, traebeculae carneae cordis, annuloplasty, infundibulectomy)
  - (c) Ventriculectomy
  - (d) Repair of atrial and ventricular septa, excluding closure of patent foramen ovale
  - (e) Excision of aneurysm of heart
  - (f) Head and neck, intracranial endarterectomy
  - (g) Other open heart surgeries, such as aortic arch repair, pulmonary endarterectomy
  - (h) Endarterectomy of aorta
  - (i) Thoracic endarterectomy (endarterectomy on an artery outside the heart)
  - (j) Heart transplantation
- (k) Repair of certain congenital cardiac anomalies, excluding closure of patent foramen ovale (e.g., tetralology of fallot, atrial septal defect (ASD), ventricular septal defect (VSD), valvular abnormality)
- (*l*) Implantation of cardiomyostimulation system (Note: Refers to cardiomyoplasty systems only; not other heart–assist systems such as pacemakers or internal cardiac defibrillators)
  - (m) Any aortic aneurysm repair (abdominal or thoracic)
  - (n) Aorta-subclavian-carotid bypass
  - (o) Aorta-renal bypass
  - (p) Aorta-iliac-femoral bypass
  - (q) Caval–pulmonary artery anastomosis
  - (r) Extracranial-intracranial (EC-IC) vascular bypass
  - (s) Coronary artery fistula
  - (t) Maze procedures, surgical or catheter
- (u) Resection of a portion of the lung (e.g., excision of an emphysematous bleb, lobectomy or segmental resection of lung). Does not include simple biopsy of lung nodule in which surrounding lung is not resected or biopsy of a thoracic lymph node.
  - (v) Mastectomy for breast cancer (not simple breast biopsy)
- (ii) If a procedure listed in this subsection is performed concurrently with the coronary artery bypass surgery, the surgery will be considered an isolated CABG and the data element coded 'Yes,' unless a procedure listed in Subsection (a)(2)(C)(i) is performed during the same surgery. These particular procedures are listed because the Office has received frequent questions regarding their coding.
  - (a) Transmyocardial laser revascularization (TMR)
  - (b) Pericardiectomy and excision of lesions of heart
  - (c) Repair/restoration of the heart or pericardium
  - (d) Coronary endarterectomy
  - (e) Pacemakers
  - (f) Internal cardiac defibrillators (ICDs)
- (g) Fem-fem cardiopulmonary bypass (a form of cardiopulmonary bypass that should not be confused with aortofemoral bypass surgery listed in Subsection (a)(2)(C)(i))
  - (3) Date of Surgery:
  - (A) Format: Date mm/dd/yyyy
  - (B) Valid Values: Between admission and computer system date
  - (C) Definition/Description: Patient date of surgery for the CABG procedure.
  - (4) Date of Birth:
  - (A) Format: Date mm/dd/yyyy
  - (B) Valid Values: Before computer system date
  - (C) Definition/Description: Patient date of birth.
  - (5) Patient Age:
  - (A) Format: Integer length 3
  - (B) Valid Values: calculated
- (C) Definition/Description: Patient age in years, at time of surgery. This should be calculated from the Date of Birth and the Date of Surgery, according to convention used in the USA (the number of birth date anniversaries reached by the date of surgery).
  - (6) Gender:
  - (A) Format: Text
  - (B) Valid Values: Male; Female
  - (C) Definition/Description: Patient gender.
  - (7) Race:
  - (A) Format: Text
  - (B) Valid Values: Caucasian; Black; Hispanic; Asian; Native American; Other
  - (C) Definition/Description: Patient race or ethnicity.
  - (8) Date of Discharge:
  - (A) Format: Date mm/dd/yyyy
  - (B) Valid Values: Between surgery and computer system date
  - (C) Definition/Description: Patient date of discharge.
  - (9) Discharge Status:
  - (A) Format: Text
  - (B) Valid Values: Alive; Dead
  - (C) Definition/Description: Patient status upon discharge from the hospitalization in which surgery occurred.

- (10) Date of Death:
- (A) Format: Date mm/dd/yyyy
- (B) Valid Values: Date of discharge or between date of discharge and computer system date
- (C) Definition/Description: Patient date of death.
- (11) Responsible Surgeon Name (3 separate fields):
- (A) Format: Surgeon Last Name text length 25

Surgeon First Name text length 20

Surgeon Middle Initial text length 1

- (B) Valid Values: Not defined.
- (C) Definition/Description: The responsible surgeon is the principal surgeon who performs the coronary artery bypass procedure, as defined in Section 97170.
  - (12) Responsible Surgeon California License Number:
  - (A) Format: Text length 10
  - (B) Valid Values: Not defined.
- (C) Definition/Description: California physician license number of responsible surgeon, assigned by the Medical Board of California of the Department of Consumer Affairs.
  - (13) Height (cm):
  - (A) Format: Real number 3.2 digits (e.g. 999.99)
  - (B) Valid Values: 20 251 cm
  - (C) Definition/Description: Height of the patient in centimeters.
  - (14) Weight (kg):
  - (A) Format: Real number 3.2 digits (e.g. 999.99)
  - (B) Valid Values: 10 250 kg
  - (C) Definition/Description: Weight of the patient in kilograms.
  - (15) Diabetes:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
  - (C) Definition/Description: The patient has a history of diabetes, regardless of duration of disease or need for anti-diabetic agents.
  - (16) Hypertension:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
  - (C) Definition/Description: The patient has a diagnosis of hypertension, documented by one of the following:
  - (i) Documented history of hypertension diagnosed and treated with medication, diet and/or exercise.
  - (ii) Blood pressure > 140 systolic or > 90 diastolic on at least 2 occasions.
  - (iii) Currently on antihypertensive medication.
  - (17) Peripheral Vascular Disease:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
- (C) Definition/Description: The patient has a history at any time prior to surgery of Peripheral Vascular Disease, as indicated by claudication either with exertion or rest; amputation for arterial insufficiency; aorto—iliac occlusive disease reconstruction; peripheral vascular bypass surgery, angio-plasty, or stent; documented abdominal aortic aneurysm (AAA), AAA repair, or stent; positive non—invasive testing documented. Excludes Cerebrovascular Disease.
  - (18) Cerebrovascular Disease:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
- (C) Definition/Description: The patient has a history at any time prior to surgery of Cerebrovascular Disease, documented by any one of the following: unresponsive coma > 24 hours; cerebrovascular accident (CVA) (symptoms > 72 hours after onset); reversible ischemic neurological deficit (RIND) (recovery within 72 hours of onset); transient ischemic attack (TIA) (recovery within 24 hours of onset); non–invasive carotid test with > 75% occlusion; or prior carotid surgery.
  - (19) Cerebrovascular Accident:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
- (C) Definition/Description: Has a history, at any time prior to surgery, of a central neurologic deficit persisting more than 72 hours. (i.e. extremity weakness or loss of motion, loss of consciousness, loss of speech, field cuts). Chart documentation of a prior diagnosis of CVA or stroke is sufficient.
  - (20) Cerebrovascular Accident Timing:
  - (A) Format: Text
  - (B) Valid Values: <=2 weeks; >2 weeks
- (C) Definition/Description: Events occurring within two weeks of the surgical procedure are considered recent (<=2 weeks); all others are considered remote (>2 weeks).
  - (21) Chronic Lung Disease:
  - (A) Format: Text
  - (B) Valid Values: No; Mild; Moderate; Severe
  - (C) Definition/Description: If the patient has chronic lung disease, the severity level according to the following classification is:
  - (i) No: No chronic lung disease present.
  - (ii) Mild: Forced expiratory volume in one second (FEV1) 60% to 75% of predicted, and/or on chronic inhaled or oral bronchodilator therapy.
  - (iii) Moderate: FEV1 50-59% of predicted, and/or on chronic steroid therapy aimed at lung disease.

- (iv) Severe: FEV1 <50% predicted, and/or room air partial pressure of exygen (pO2) <60 or room air partial pressure of carbon dioxide (pCO2) > 50.
  - (22) Immunosuppressive Treatment:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
- (C) Definition/Description: Patient has used any form of immunosuppressive therapy (i.e., systemic steroid therapy) within 30 days preceding the operative procedure. Does not include topical applications and inhalers.
  - (23) Hepatic Failure:
  - (A) Format: Text length 3
  - (B) Valid Values: Yes; No
- (C) Definition/Description: The patient has cirrhosis, hepatic failure, acute hepatitis or "shock liver" and has a bilirubin greater than 2mg/dl and a serum albumin less than 3.5 grams/dl.
  - (24) Dialysis:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
  - (C) Definition/Description: The patient is on dialysis preoperatively.
  - (25) Last Creatinine Level Preop (mg/dl):
  - (A) Format: Real number 2.1 digits (e.g. 99.9)
  - (B) Valid Values: 0.1 30
- (C) Definition/Description: The most recent creatinine level prior to day of surgery. A creatinine level should be collected on all patients for consistency, even if they have no prior history.
  - (26) Left Main Disease (% Stenosis):
  - (A) Format: Integer length 3
  - (B) Valid Values: 0 100
  - (C) Definition/Description: Percentage of compromise of vessel diameter in any angiographic view.
  - (27) Number of Diseased Coronary Vessels:
  - (A) Format: Text
  - (B) Valid Values: None; One; Two; Three
- (C) Definition/Description: The number of major coronary vessel systems (Left anterior descending (LAD) system, Circumflex system, and/or Right system) with >50% narrowing in any angiographic view. NOTE: Left main disease (>50%) is counted as TWO vessels (LAD and Circumflex). For example, left main and right coronary artery (RCA) would count as three total.
  - (28) Mitral Insufficiency:
  - (A) Format: Text
  - (B) Valid Values: None; Trivial; Mild; Moderate; Severe
  - (C) Definition/Description: If there is evidence of mitral valve regurgitation, indicate the severity level.
  - (29) Ejection Fraction (%):
  - (A) Format: Integer length 2
  - (B) Valid Values: 5 90
- (C) Definition/Description: The percentage of blood emptied from the ventricle at the end of the contraction. Use the most recent determination prior to intervention.
  - (30) Ejection Fraction Method:
  - (A) Format: Text
  - (B) Valid Values: LV Gram; Radionuclide; Estimate; ECHO
  - (C) Definition/Description: Method of obtaining ejection fraction measurement information:
  - (i) LV Gram: Left Ventriculogram.
  - (ii) Radionuclide: MUGA Scan.
  - (iii) Estimate: From other calculations, based upon available clinical data.
  - (iv) ECHO: Echocardiogram.
  - (31) Myocardial Infarction:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
- (C) Definition/Description: Refers to any myocardial infarction (MI) in the past. For MIs prior to the current hospitalization for which detailed records are not available, chart documentation in which a clinician caring for the patient diagnosed an MI is sufficient. For MIs during the current hospitalization for which detailed records are available, conditions i and ii below must be met:
  - (i) The patient must have been diagnosed with a myocardial infarction (ST elevation or non ST elevation) by a clinician caring for patient.
  - (ii) At least 1 of the 3 following biochemical indicators for detecting myocardial necrosis must be present:
  - (a) Troponin T or I:
- (1) Maximal concentration of troponin T or I exceeding the MI diagnostic limit (99th percentile of the values for a reference control group, as defined in Subsection (31)(C)(iii)) on at least one occasion during the first 24 hours after the index clinical event.
  - (b) CK-MB:
- (1) Maximal value of CK-MB more than two times the upper limit of normal on at least one occasion during the first 24 hours after the index clinical event.
- (2) Maximal value of CK–MB, preferable CK–MB mass, exceeding 99th percentile of the values for a reference control group, as defined in Subsection (31)(C)(iii), on two successive samples during the first 24 hours after the index clinical event.
  - (c) Total CK:

- (1) In the absence of availability of a troponin or CK–MB assay, total CK more than two times the upper limit of normal (99th percentile of the values for a reference control group, as defined in Subsection (31)(C)(iii)), or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK–MB.
  - (iii) Reference control values (MI diagnostic limit and upper limit of normal):
- (a) Reference values must be determined in each laboratory by studies using specific assays with appropriate quality control, as reported in peer–reviewed journals. Acceptable imprecision (coefficient of variation) at the 99th percentile for each assay should be defined as less than or equal to 10 percent. Each individual laboratory should confirm the range of reference values in their specific setting.
  - (32) Myocardial Infarction Timing:
  - (A) Format: Text
  - (B) Valid Values: <=6 hours; >6 but <24 hours; 1–7 days; 8–21 days; >21 days.
  - (C) Definition/Description: Time period between the last documented myocardial infarction and the CABG surgery.
  - (33) Arrhythmia:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
- (C) Definition/Description: A preoperative arrhythmia present within two weeks prior to the procedure, by clinical documentation of any one of the following:
  - (i) Atrial fibrillation/flutter requiring medication.
  - (ii) Heart block.
  - (iii) Sustained Ventricular Tachycardia or Ventricular Fibrillation requiring cardioversion and/or intravenous amiodarone.
  - (34) Arrhythmia Type:
  - (A) Format: Text
  - (B) Valid Values: Sust VT/VF; Heart Block; Afib/Flutter
  - (C) Definition/Description: The type of arrhythmia present within two weeks prior to the procedure is:
  - (i) Sustained Ventricular Tachycardia or Ventricular Fibrillation requiring cardioversion and/or intravenous amiodarone.
  - (ii) Heart Block.
  - (iii) Atrial fibrillation/flutter requiring medication.
  - (35) Cardiogenic Shock:
  - (A) Format: Text
  - (B) Valid Values: Yes: No
  - (C) Definition/Description: The patient, at the time of procedure, is in a clinical state of hypoperfusion according to either of the following criteria:
  - (i) Systolic blood pressure (BP) < 80 and/or Cardiac Index (CI) < 1.8 despite maximal treatment.
  - (ii) Intravenous inotropes and/or intra-aortic balloon pump (IABP) necessary to maintain Systolic BP > 80 and/or CI > 1.8.
  - (36) Angina:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
  - (C) Definition/Description: The patient has ever had angina pectoris.
  - (37) Angina Type:
  - (A) Format: Text
  - (B) Valid Values: Stable; Unstable
  - (C) Definition/Description: The type of angina present within 24 hours prior to the CABG surgery is:
  - (i) Stable: Angina not meeting unstable criteria below that is controlled by oral or transcutaneous medication.
  - (ii) Unstable: Requires continuous hospitalization from the episode until surgery and one of the following:
  - (a) Angina at rest.
  - (b) New onset angina in past 2 months of at least Canadian Cardiovascular Society (CCS) Class III.
- (c) Increasing angina in past 2 months angina that has become more frequent, longer in duration, or lower in threshold; and increased by greater than or equal to 1 CCS class to at least CCS Class III severity.
  - (38) CCS Classification:
  - (A) Format: Text
  - (B) Valid Values: 0; I; II; III; IV
- (C) Definition/Description: Canadian Cardiovascular Society (CCS) Classification. This classification represents level of functional status related to frequency and intensity of angina. The CCS may not be the same as the NYHA classification for the same evaluation time period. Code the highest class leading to episode of hospitalization and/or intervention:
  - (i) 0= No angina.
- (ii) I = Ordinary physical activity, such as walking or climbing the stairs does not cause angina. Angina may occur with strenuous, rapid or prolonged exertion at work or recreation.
- (iii) II = There is a slight limitation of ordinary activity. Angina may occur with moderate activity such as walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals or in the cold, in the wind, or under emotional stress, or walking more than two blocks on the level, and climbing more than one flight of stairs at normal pace under normal conditions.
- (iv) III = There is marked limitation of ordinary physical activity. Angina may occur after walking one or two blocks on the level or climbing one flight of stairs under normal conditions at a normal pace.
  - $(v)\ IV = There\ is\ inability\ to\ carry\ on\ any\ physical\ activity\ without\ discomfort;\ angina\ may\ be\ present\ at\ rest.$
  - (39) Congestive Heart Failure:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
- (C) Definition/Description: The patient had symptoms that occurred within 2 weeks prior to surgery. This does not include patients with chronic or stable non–symptomatic compensated congestive heart failure (CHF). The patient has one or more of the following:

- (i) Paroxysmal nocturnal dyspnea (PND).
- (ii) Dyspnea on exertion (DOE) due to heart failure.
- (iii) Chest X-Ray (CXR) showing pulmonary congestion.
- (iv) Pedal edema or dyspnea and receiving diuretics or digoxin.
- (40) NYHA Classification:
- (A) Format: Text
- (B) Valid Values: I; II; III; IV
- (C) Definition/Description: New York Heart Association (NYHA) Classification represents the overall functional status of the patient in relationship to both congestive heart failure and angina. The NYHA may not be the same as the CCS classification for the same evaluation period. Code the highest level leading to episode of hospitalization and/or procedure.
- (i) I = Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
- (ii) II = Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitations, dyspnea or anginal pain.
- (iii) III = Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity results in fatigue, palpitations, dyspnea, or anginal pain.
- (iv) IV = Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.
  - (41) Number of Prior Cardiac Operations Requiring Cardiopulmonary Bypass:
  - (A) Format: Integer length 1
  - (B) Valid Values: 0-9
- (C) Definition/Description: Prior to this operation, the number of cardiac surgical operations performed on this patient utilizing cardiopulmonary bypass.
  - (42) Number of Prior Cardiac Operations Without Cardiopulmonary Bypass:
  - (A) Format: Integer length 1
  - (B) Valid Values: 0-9
- (C) Definition/Description: Prior to this operation, the number of cardiac surgical operations performed on this patient without cardiopulmonary bypass.
  - (43) Status of the Procedure:
  - (A) Format: Text
  - (B) Valid Values: Emergent/Salvage; Emergent; Urgent; Elective
  - (C) Definition/Description: The status that best describes the clinical status of the patient at the time of surgery.
  - (i) Emergent/Salvage: The patient is undergoing cardiopulmonary resuscitation en route to the operating room or prior to anesthesia induction.
  - (ii) Emergent: The patient's clinical status includes any of the following:
  - (b) Ischemic dysfunction (any of the following):
  - $(2) \ Ongoing \ is chemia \ including \ rest \ angina \ despite \ maximal \ medical \ the rapy \ (medical \ and/or \ intra-a ortic \ balloon \ pump \ (IABP));$
  - (3) Acute evolving Myocardial Infarction within 24 hours before surgery; or
  - (4) Pulmonary edema requiring intubation.
  - (b) Mechanical dysfunction (either of the following):
  - (1) Shock with circulatory support; or
  - (2) Shock without circulatory support.
  - (iii) Urgent: ALL of the following conditions are met:
  - (a) Not elective status
  - (b) Not emergent status
  - (c) Procedure required during same hospitalization in order to minimize chance of further clinical deterioration.
- (d) Worsening, sudden chest pain; congestive heart failure (CHF); acute myocardial infarction (AMI); coronary anatomy; IABP; unstable angina (USA) with intravenous nitroglycerin; rest angina, valve dysfunction; or aortic dissection.
- (iv) Elective: The patient's status has been stable in the days or weeks prior to the operation. The procedure could be deferred without increased risk of compromised cardiac outcome.
  - (44) Cardiopulmonary Bypass Used:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
  - (C) Definition/Description: Use of cardiopulmonary bypass (CPB) at any time during the procedure.
  - (45) Conversion to Cardiopulmonary Bypass:
  - (A) Format: Text
  - (B) Valid Values: Yes; No
  - (C) Definition/Description: The patient needed to be placed on cardiopulmonary bypass (CPB) after the off-pump procedure was attempted.
  - (46) Primary Incision:
  - (A) Format: Text
- (B) Valid Values: Full Sternotomy; Partial Sternotomy; Transverse Sternotomy; Right Vertical Parasternal; Left Vertical Parasternal; Right Anterior Thoracotomy; Left Anterior Thoracotomy; Posterolateral Thoracotomy; Xiphoid; Epigastric; Subcostal
  - (C) Definition/Description: The primary incision used as the initial intention for treatment:
  - (i) Full Sternotomy
  - (ii) Partial Sternotomy
  - (iii) Transverse Sternotomy
  - (iv) Right Vertical Parasternal

- (v) Left Vertical Parasternal
- (vi) Right Anterior Thoracotomy
- (vii) Left Anterior Thoracotomy
- (viii) Posterolateral Thoracotomy
- (ix) Xiphoid
- (x) Epigastric
- (xi) Subcostal
- (47) Cardioplegia:
- (A) Format: Text
- (B) Valid Values: Yes: No
- (C) Definition/Description: Cardioplegia was used.
- (48) Internal Mammary Artery(ies) Used as Grafts:
- (A) Format: Text
- (B) Valid Values: Left IMA; Right IMA; Both IMAs; No IMA
- (C) Definition/Description: Internal Mammary Artery(ies) (IMA) used for grafts, if any.
- (i) Left IMA
- (ii) Right IMA
- (iii) Both IMAs
- (iv) No IMA
- (49) Prior Percutaneous coronary intervention (PCI):
- (A) Format: Text
- (B) Valid Values: Yes; No
- (C) Definition/Description: Percutaneous coronary-intervention (PCI) was done at any time prior to this surgical procedure (which may include during the current admission). PCI includes percutaneous transluminal coronary angioplasty (PTCA), intracoronary fibrinolysis without PTCA, laser recanalization, stent implantation, rheolysis with angiojet, brachytherapy, and other catheter-based percutaneous recanalization techniques.
  - (50) Interval from prior PCI to Surgery:
  - (A) Format: Text
  - (B) Valid Values: <=6 hours: > 6 hours
  - (C) Definition/Description: The time between PCI and surgical repair of coronary occlusion:
  - $(i) \le 6 \text{ hours}$
  - (ii) > 6 hours
  - (51) Facility Identification Number:
  - (A) Format: Text length 6
  - (B) Valid Values: Not defined.
  - (C) Definition/Description: The six-digit facility identification number assigned by the Office, as defined in Section 97170.
- (b) If a value for a data element, other than data elements specified in Subsection (b)(1), is unknown or not applicable, a hospital may submit the record without a value for that data element. The Office may require a hospital to provide data to replace missing data element values, pursuant to Section 97192.
- (1) A valid value must be submitted for the following data elements: Facility Identification Number, Medical Record Number, Responsible Surgeon Name, Responsible Surgeon California License Number, Isolated CABG, Date of Surgery, Date of Discharge and Discharge Status.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

### <T22S97176>

### § 97176. Reporting Periods and Due Date.

- (a) During each calendar year there are two reporting periods. The first reporting period is January 1 through June 30; the second period is July 1 through December 31.
- (b) If there has been a change in the licensure of a hospital, the effective date of a change in licensee shall constitute the start of the reporting period for the new licensee, and this first reporting period shall end on June 30 or December 31, whichever occurs first. The final day of the reporting period for the previous licensee shall be the last day their licensure was effective.
  - (c) A hospital shall file a report by the date the report is due. The due date is 90 days after the end of a reporting period.
- (d) When a report due date is a Saturday, Sunday, or a state observed holiday, a report shall be considered timely if filed on the next business day. NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

# <T22S97178>

#### § 97178. Extensions to File Report.

- (a) Extensions are available to a hospital that is unable to file a report by the due date. The Office shall grant in extensions no more than a cumulative total of 30 days per report. The Office shall grant no more than 3 extensions per report, including an automatically provided extension.
- (b) If a hospital files a report before the due date of an extension, the days not used will be applied to the number of remaining extension days for the report.

- (c) The Office shall grant to a hospital one automatic extension of 10 days for a report that has not been filed by a due date established pursuant to Section 97176 or Subsection (b) of Section 97186, to the extent that extension time is available.
- (d) In addition to the automatic extensions provided for in Subsection (c), a hospital may request extensions. A request for an extension shall be filed on or before the due date of a report and supported by a written justification that provides sufficient cause for the approval of the extension request. The Office may seek additional information from a requesting hospital. To provide the Office a basis to determine sufficient cause, a written justification shall include a factual statement indicating:
  - (1) the actions taken by the hospital to produce the report by the due date;
  - (2) those factors that prevent completion of the report by the due date; and
  - (3) the actions and the time (days) needed to accommodate those factors.
- (e) The Office shall respond in writing by either granting a hospital what is determined to be a reasonable extension or disapproving the request. If a hospital has been granted an extension, the Office shall notify the hospital of the new due date for the report.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

#### HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

## <T22S97180>

#### § 97180. Method of Data Collection.

- (a) A hospital shall use one of the following methods to collect the required data elements, as specified in Section 97174, for a report:
- (1) The CCORP data collection tool,
- (2) A National Society of Thoracic Surgeons (STS) approved software vendor tool developed for collection of CCORP data, or
- (3) Another data collection system that generates an electronic report, which meets the data requirements in Section 97174 and the format specifications in Section 97182.
- (b) If a hospital does not use the CCORP data collection tool or a STS approved software vendor tool to collect the required data elements for a report, the hospital may submit to the Office a test report before it files its first report using an alternate system. The test report should contain at least one record that meets the data requirements in Section 97174 and the format specifications in Section 97182. The hospital should provide the Office the test report 90 days prior to the due date for the hospital's next report. The Office will notify the hospital whether the submitted test report met the data requirements in Section 97174 and the format specifications in Section 97182.
- (c) The Office shall furnish each hospital, upon request and at no cost, a copy of the CCORP data collection tool.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

#### HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

### <T22S97182>

#### § 97182. Report Format.

- (a) A hospital shall file a report to the Office on one of the following media:
- (1) IBM PC-compatible diskette, or
- (2) compact disk (CD).
- (b) A hospital shall file a report in a comma-delimited ASCII file with the following format specifications:
- (1) Labels identifying each data element on the first data row, and
- (2) Data elements listed in the order set forth in Section 97174.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

#### HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

# <T22S97184>

#### § 97184. Report Acceptance Criteria.

The following requirements must be met for the Office to accept a report:

- (a) The Office is able to read the diskette or compact disk (CD) on which the report is submitted.
- (b) The diskette or CD contains data for only one hospital and one reporting period.
- (c) CCORP Surgeon Certification Forms are complete and included with the report, pursuant to Section 97188.
- (d) A completed CCORP Hospital Certification Form is included with the report, pursuant to Section 97190.
- (e) The facility identification number on each of the records in the report is consistent with the facility identification number specified on the CCORP Hospital Certification Form.
- (f) The patient discharge date on each of the records in the report is consistent with the report period specified on the CCORP Hospital Certification Form.
- (g) The report contains data for the specified reporting period, and contains the number of records stated on the CCORP Hospital Certification Form.
  - (h) Each record in the report contains data values for the data elements specified in Subsection (b)(1) of Section 97174.
  - (i) The report complies with the format specifications set forth in Sections 97182.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

#### HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

## <T22S97186>

#### § 97186. Report Acceptance or Rejection.

- (a) The Office shall accept or reject each report within 60 days of receipt. A report shall be considered not filed on the date that a hospital receives notice from the Office that a report has been rejected.
- (b) When the Office rejects a report upon initial submission by a hospital, the Office shall provide a hospital 10 days to resubmit the report. The Office shall notify a hospital of the new due date for the report.
- (c) When the Office rejects a report a second or subsequent time, the Office may provide a hospital 5 days to resubmit the report. The Office shall notify a hospital of the new due date for the report.
- (d) For additional time to resubmit a report, a hospital also may request extensions, pursuant to Section 97178.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

### <T22S97188>

### § 97188. Surgeon Certification of Data.

- (a) Each surgeon identified as a responsible surgeon in a report shall attest to the accuracy of the reported data for his or her CABG surgeries using the CCORP Surgeon Certification Form (OSH–CCORP 415 (New 10/02)).
- (b) The CCORP Surgeon Certification Form (OSH–CCORP 415 (New 10/02)) shall include the following information: the surgeon's name, the surgeon's California physician license number, the hospital name, the facility identification number, as defined in Section 97170, the reporting period's beginning and ending dates, the number of records in the report, and the following Statement of Certification, to be signed by the surgeon:
- I, (name of surgeon), affirm that the cases assigned to me in this California CABG Outcomes Reporting Program report are accurate, and that I have reviewed these data for accuracy and completeness. I also understand that these data, after any corrections or revisions required by the Office of Statewide Health Planning and Development, will be used to compute my risk-adjusted mortality rate for coronary artery bypass graft surgery, and that the Office of Statewide Health Planning and Development will assign data elements with invalid or missing values the lowest risk value as observed in the most current risk-adjustment model for predicting mortality.

Name:	
Address:	
Telephone:	
Email:	
Signature:	
Dated:	

- (c) If a responsible surgeon does not complete and sign a CCORP Surgeon Certification Form (OSH–CCORP 415 (New 10/02)), a hospital shall provide the surgeon's name and physician license number as part of the CCORP Hospital Certification Form (OSH–CCORP 416 (New 10/02)), pursuant to Section 97190.
- (d) With a report, a hospital shall file with the Office all completed and signed CCORP Surgeon Certification Forms (OSH–CCORP 415 (New 10/02)).
- (e) A hospital may obtain copies of the CCORP Surgeon Certification Form (OSH–CCORP 415 (New 10/02)) on the Office's web site or by contacting the Office.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

## <T22S97190>

### § 97190. Hospital Certification of Data.

- (a) With a report, a hospital shall file with the Office a completed CCORP Hospital Certification Form (OSH–CCORP 416 (New 10/02)), including the following information: the hospital name, the facility identification number, as defined in Section 97170, the reporting period's beginning and ending dates, the number of records in the report, the data collection tool used (CCORP, Society of Thoracic Surgeons, or other), the number of CCORP Surgeon Certification Forms (OSH–CCORP 415 (New 10/02)) included with the report, the number of responsible surgeons who did not complete a CCORP Surgeon Certification Form for the report, and the Statement of Certification, to be signed by the hospital's Chief Executive Officer or designee, as defined in Subsection (e) of Section 97170.
- (b) If a responsible surgeon does not complete and sign a CCORP Surgeon Certification Form (OSH–CCORP 415 (New 10/02)) pursuant to Section 97188, a hospital shall provide the surgeon's name and physician license number on the CCORP Hospital Certification Form (OSH–CCORP 416 (New 10/02)), as part of the Statement of Certification.
- (c) If all responsible surgeons complete and sign a CCORP Surgeon Certification Form (OSH–CCORP 415 (New 10/02)) pursuant to Section 97188, a hospital shall affirm that no surgeons failed to complete and sign a CCORP Surgeon Certification Form by writing 'none' on the CCORP Hospital Certification Form (OSH–CCORP 416 (New 10/02)), as part of the Statement of Certification.
  - (d) The Statement of Certification, to be signed by the hospital's Chief Executive Officer (CEO) or designee shall state:
- I, (name of CEO or designee), certify under penalty of perjury as follows: That I am an official of (name of hospital) and am duly authorized to submit this California CABG Outcomes Reporting Program report, and that, to the extent of my knowledge and information, the accompanying data are true and correct, and that the definitions of data elements as set forth in Section 97174 of Title 22 of the California Code of Regulations have been followed by this hospital.

I certify that the following surgeon(s), if any, did not complete a CCORP Surgeon Certification Form and that each was provided the data for the cases assigned to him or her in this California CABG Outcomes Reporting Program report and was given an opportunity to review the data for accuracy and completeness.
(Surgeon name) (California physician license number)
I also certify that each surgeon(s) listed above was informed that the data for his or her cases, after any corrections or revisions required by the Office of Statewide Health Planning and Development, will be used to compute his or her risk-adjusted mortality rate for coronary artery bypass graft surgery, and that the Office of Statewide Health Planning and Development will assign data elements with invalid or missing values the lowest isk value as observed in the most current risk-adjustment model for predicting mortality.
Name:
Title:
Address:
Telephone:
Email:
Signature:
Dated:
(e) A hospital may obtain copies of the CCORP Hospital Certification Form (OSH–CCORP 416 (New 10/02)) on the Office's web site or by conacting the Office.
NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

## <T22S97192>

### § 97192. Correction of Data.

- (a) After a report has been accepted pursuant to Section 97186, a hospital may be required to provide the Office with data to replace invalid or missing data element values.
- (b) The Office shall notify each hospital of its final opportunity to make corrections and revisions to submitted data at least 60 days before the Office conducts analyses to identify hospitals and surgeons for possible audit. From the date of notification, a hospital shall have 30 days to submit all corrections and revisions to the Office. The Office may require documentation to support data changes requested by a hospital.
- (c) If a hospital fails to provide a valid value, as set forth in Section 97174, or provides no value for a data element in a record, by the end of the 30–day period, the Office shall assign the data element in the record the lowest risk value as observed in the most current risk adjustment model. Note: Authority cited: Section 128810, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

### <T22S97194>

### § 97194. Audit Procedure.

- (a) The Office may conduct periodic audits of a hospital's patient medical records for its CABG surgery patients. Audits may, at the Office's discretion, be performed at the hospital location.
- (b) The Office shall notify a hospital a minimum of 2 weeks before the date of an audit. Upon notification that an audit is planned, a hospital shall designate a person to serve as the audit contact person. A hospital shall provide to the Office the contact person's name, title, telephone number, and electronic mail address.
- (c) A hospital shall retrieve and make available the requested patient medical records for an audit, and if requested by the Office, provide a reasonable space in which the Office may conduct an audit.
- (d) Data abstracted during an audit may, at the Office's discretion, replace data for a given record submitted in a report filed by a hospital. Replacement data shall be used in calculating risk-adjusted mortality rates for hospitals and physicians.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

## <T22S97196>

### § 97196. Hospital Data Contact Person.

- (a) Each hospital at which CABG surgeries are performed shall designate a CCORP data contact person. A hospital shall notify CCORP in writing (hardcopy or electronic mail) within 30 days of the effective date of this regulation or within 30 days of beginning or resuming operation. A notification shall include the designated person's name, title, telephone number(s), mailing address, and electronic mail address.
- (b) A hospital shall notify CCORP in writing (hardcopy or electronic mail) within 30 days after any change in the person designated as the CCORP data contact person, or in the title, telephone number(s), mailing address, or electronic mail address, of the individual.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).

# <T22S97198>

#### § 97198. Failure to File a CABG Report.

- (a) A civil penalty of one hundred dollars (\$100) per day shall be assessed to a hospital that does not file a report as required by this Article by the date it is due. No penalty shall be imposed during an extension period as provided in Section 97178 or a resubmission period as provided in Section 97186.
  - (b) Within 15 days after the date a report is due, the Office shall notify a hospital that has not filed its report of the penalties.
  - (c) Assessed penalties may be appealed pursuant to Section 97052 of Title 22 of the California Code of Regulations.

NOTE: Authority cited: Section 128810, Health and Safety Code. Reference: Section 128745, Health and Safety Code.

HISTORY

1. New section filed 4-29-2003; operative 4-29-2003 pursuant to Government Code section 11343.4 (Register 2003, No. 18).